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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/829,563 | 04/11/2001 | Jack V. Smith | | 7743 |

7590
JACK V. SMITH
P.O. BOX 156
Arden, NC 28704

09/23/2003

EXAMINER

BAKER, MAURIE GARCIA

| ART UNIT | PAPER NUMBER |
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1639

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE
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| SERIAL NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
|---------------|-------------|-----------------------|---------------------|
| 09/829,563 | 04/11/01 | SMITH | |

| EXAMINER | |
|----------------------------|--------------|
| Maurie Garcia Baker, Ph.D. | |
| ART UNIT | PAPER NUMBER |
| 1639 | 9 |

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application

Commissioner of Patents

Please see attached Notice of Non-Responsive Amendment.

DETAILED ACTION

Please note that the Art Unit where this application is located is **Art Unit 1639**, not 7743 as noted on the correspondence.

1. In the Response filed June 2, 2003, Applicant notes that they do not believe that it is necessary to secure the services of a registered patent attorney or agent as suggested by the examiner in the last action. However, the examiner maintains that this would afford the maximum protection for the invention disclosed and assist in the prosecution of the instant case. Again, the Office cannot aid in selecting an attorney or agent and Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

2. Applicant also asks for "constructive assistance". The examiner has attempted to provide such in all of the office actions in the instant case, including that set forth below. Please especially note the examiner comments in paragraphs 6-13 of this action.

Notice of Non-Responsive Amendment

3. The amendment filed on June 2, 2003 does not comply with the requirements of 37 CFR 1.121. In June of 2003, Applicant had two options for filing amendments. The first was the method of providing clean and marked-up versions of the claims. This was not done. The second option for filing amendments was as is delineated in **Amendments in a Revised Format**

Now Permitted, 1267 Off. Gaz. Pat. Office 106 (February 25, 2003). This procedure was not complied with either. Thus Applicant followed neither of the correct amendment procedures that were available as of June 2, 2003 and the amendment is non-responsive.

4. Note that now Applicant **must** comply with the Revised format referred to in 1267 Off. Gaz. Pat. Office 106 as this has been made **mandatory** as of July 30, 2003. See **Changes To Implement Electronic Maintenance of Official Patent Application Records, Final Rule** published at 68 Fed Reg 38611 (30 June 2003). This is further explained on the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/moreinfoamdtprac.htm> .

5. Since the reply filed on June 2, 2003 appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance with 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Proposed Amendments

6. Although the amendments filed June 2, 2003 have not been entered, the following is noted to assist in the prosecution of the instant case.

7. It appears that Applicant has again cancelled all claims drawn to the elected invention and presented only claims drawn to a non-elected invention which is also non-responsive (MPEP

§ 821.03). The remaining claims are not readable on the elected (i.e. previously examined) invention for the following reasons. Note that clarification of the below problems in response to this action will help in the prosecution of the instant case.

8. Applicant *originally* claimed a “method for determining an analyte of interest using nucleounits targeted to said analyte of interest”. This method had steps of “identifying a nucleounit from a mixture of synthetic random sequences of nucleounit libraries”, contacting the analyte with said mixture, removing the unbound nucleounits by partitioning, amplifying the remaining nucleounits by PCR, conjugating the nucleounits to an indicator and then using the conjugate for detecting the analyte of interest.

9. Applicant *now* claims methods “for the detection of Prostate Specific Antigen” that contain the above-mentioned steps as well as additional steps. Independent claim 8 has additional steps of “preparing a dry chemistry test means”, drying such means and dipping it into the sample to detect the analyte via a color response. Newly added independent claim 12 has additional steps of using a “chemistry autoanalyzer” with various transferring, aliquoting and incubating steps, and detection by absorbance at certain wavelengths.

10. It is unclear that independent claims 8 and 12 are the same method as originally claimed as it is unclear in the additional step (A) of each method that the “nucleounit indicator conjugate” is the same entity that is identified in the previous portion of the claim. That is, it appears that

claims 8 and 12 both contain *two* methods therein and the relationship between the two methods is unclear.

11. Moreover, independent claim 8 and independent claim 12 represent methods that are different *from each other*. Use of “a dry chemistry test means” is different than using a “chemistry autoanalyzer”. Thus, the newly added claims represent two distinct inventions. The methods use *completely different steps and reagents*. Therefore, the inventions each have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches.


12. Thus, if it is made clear that claims 8 and/or 12 represent the same invention as was previously examined, there would then be the need to issue a Restriction Requirement between the two different methods if claims to both inventions are presented in a subsequently filed amendment. See MPEP 811.02: Since 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. *Ex parte Benke*, 1904 C.D. 63, 108 O.G. 1588 (Comm'r Pat. 1904).

13. Also, Applicant is again reminded of 37 CFR 1.142(b) and MPEP § 821.03. Once Applicant has received an action on the merits for the *originally presented* invention, this invention has been constructively elected by original presentation for prosecution on the merits.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
September 20, 2003



MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER